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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Robert J. Garabedian

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EXAMINER

GEDEON, BRIAN T

ART UNIT

PAPER NUMBER

3766

MAIL DATE

DELIVERY MODE

10/21/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/799,271	Applicant(s) GARABEDIAN ET AL.	
	Examiner Brian T. Gedeon	Art Unit 3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 July 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9, 18-23, 37-47, 126-136 and 138-177 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 37-47, 126-136 and 138-177 is/are allowed.
- 6) ☒ Claim(s) 1-9 and 18-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. This action is in response to the amendment after non-final filed 15 July 2008.

Response to Arguments

2. Applicant's arguments, see Remarks, filed 15 July 2008, with respect to claims 37-47, 126-145 and 162-172 have been fully considered and are persuasive. The rejection of claims 126-145 and 162-172 has been withdrawn.

3. Applicant's arguments, see Remarks, filed 15 July 2008, with respect to the rejection(s) of claim(s) 1, 2, 4-10, 18, and 19 under 35 U.S.C. 102(e) as being anticipated by Vinup et al. (US Patent no. 7,072,719) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made under 35 U.S.C. 103(a) as being anticipated by Vinup et al. (US Patent no. 7,072,719).

Claim Objections

4. The objection made to claims 8, 9, 18, and 19 for minor informalities has been withdrawn in view of the amendment.

Allowable Subject Matter

5. Claims 37-47 and 126-177 are allowed.

The following is a statement of reasons for the indication of allowable subject matter: The cited prior art does not teach or suggest disengaging the second lead body from the first lead body.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1, 2, 4-9, 18, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vinup et al. (US Patent no. 7,072,719).

In regard to claim 1, Vinup et al. disclose a neurological stimulation system 20 with stimulation leads 24 and 26 with interlocking elements 23, col 1 lines 28-39. Figures 2-5 show a plurality of medical leads which allow for implantation of paddle or surgical style leads using percutaneous methods without the use of a large needle or introducer, col 2 lines 40-49. The leads are axially engaged to one another. The lead bodies are axially engaged to one another by a wide variety of complementary coupling geometries, such as a rail and groove embodiment as depicted in figures 6a-7b, col 3 lines 46-54. Vinup et al. disclose that the method for inserting the neurological leads involves introducing a first lead through a needle or introducer, then engaging the coupling mechanism (detail 46) of the second lead body using the first lead body

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coupling mechanism (detail 40) as a guide, col 3 line 55 – col 4 line 2. In view of the method described by Vinup for insertion of the second lead body using the first lead body as a guide, it is considered that the second lead is being slidably inserted along the first lead, wherein the leads can be slidably engaged along the rail and groove coupling mechanism. Figures 2-5, particularly figure 2, depict the distal end of lead 26 extending beyond the distal end of lead 24. The Examiner recognizes and agrees with Applicant that this depiction does not speak with regard to the actual length of the leads, since the proximal ends of the leads are not shown; thus there is no express or inherent teaching that the leads are of different lengths, nor even of the same length. However, in view of these depictions, the Examiner considers that one of ordinary skill in the art would be motivated to modify the lead 26 so that it would be longer than lead 24 (i.e., 24 would shorter) so that the proximal ends of lead 24 and 26 would terminate in the same location thus allow connection with a stimulation source without requiring a lead extender for and offset lead. If leads 24 and 26 were of the same length, and situated as in figure 2, the leads would be offset, which would result in offset proximal ends, various lengths of lead extenders would be required in order to properly align the proximal ends to make connection with the stimulation source, which would not be an optimal situation during implantation especially if the multiple lead embodies in figures 3 and 4 were used. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify lead 26 such that it would be longer than lead 24 in order to facilitate connection with a stimulation source.

Further in regard to claim 1, figure 1 illustrates that lead bodies 24 and 26 extending from the lower spine namely the proximal end of leads bodies 24 and 26 extend from the lower spine where they are coupled to a neurostimulation pulse generator housing 22. The Examiner considers the leads of Vinup et al. to be capable of performing such a function, since it is known in the art that neurostimulation pulse generator housings are sometimes implanted and sometimes kept external to the patient wherein the leads would have to extend through an opening in the patient's skin in order to connect to the generator housing.

In regard to claim 2, the lead bodies are substantially cylindrically shaped, figures 6a-6c.

In regard to claims 4, 5, and 7, the stimulation leads of Vinup et al. have at least one electrode, col 2 lines 50-58.

In regard to claim 6, figures 2-4 of Vinup et al. show the electrodes 34 facing in a single direction when the leads are engaged with one another.

In regard to claims 8 and 9, the complementary coupling mechanisms 23, are rail and groove embodiment, extending axially along the leads, col 3 lines 46-54.

In regard to claim 10, figures 2-5 show the first and second leads being of different lengths.

In regard to claim 18, figures 2-4, 6a-6c, and 9a-9c, shows various embodiments where a plurality of leads can be engaged to one another by means of complementary coupling mechanisms being axially located on both sides of a single lead.

In regard to claim 19, a neurological stimulator 22 is coupled to the stimulation leads, col 2 lines 29-32.

8. Claims 3, 20-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vinup et al. (US Patent no. 7,072,719) as applied to claim 1, and further in view of Cross, Jr. et al. (US Patent no. 6,578,733 – hereinafter Cross).

In regard to claim 3, Vinup et al. disclose the claimed invention with the exception of specific dimensions for the cross-sectional area of the first and second elongated bodies. It would have been obvious to one with ordinary skill in the art at the time the invention was made to utilize 5 mm or less for the said elongated bodies since our reviewing courts have held that where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device. *Gardner v. TEC Systems, Inc.*, 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), cert. denied, 469 U.S. 830, 225 USPQ 232 (1984).

In regard to claims 20 and 22, Vinup et al. describe the invention as claimed including inserting a first stimulation lead at a predetermined position, then guides at least a second stimulation lead along the first stimulation lead, wherein the leads are coupled together by means of a complementary coupling mechanism, col 3 lines 46-67. The leads are configured to be coupled together and stimulate neurological tissue (i.e., nerves or muscle tissue) in a desired location, col 2 lines 33-36. Vinup et al. disclose that the method for inserting the neurological leads involves introducing a first lead

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through a needle or introducer, then engaging the coupling mechanism (detail 46) of the second lead body using the first lead body coupling mechanism (detail 40) as a guide, col 3 line 55 – col 4 line 2. In view of the method described by Vinup for insertion of the second lead body using the first lead body as a guide, it is considered that the second lead is being slidably inserted along the first lead, wherein the leads can be slidably engaged along the rail and groove coupling mechanism. However, Vinup et al. do not teach that the leads are inserted into the epidural space around the spinal cord. Cross, in a similar field of endeavor, discloses a percutaneous surgical lead, wherein two lead bodies 12 and 14 are axially coupled together and inserted into the spinal cord. Cross also teaches that stimulation of the spinal cord often is accomplished by implanting medical leads into the epidural space of the spinal cavity, col 1 lines 20-23. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Vinup et al. with the teachings of Cross since Vinup et al. teach that the stimulation lead can percutaneously be implanted in a desired spot to stimulate nerve tissue and Cross teaches that it is known in the art to stimulate nerve tissue in the epidural space of the spinal cord by means of an electrical lead, particularly electrical leads that are axially coupled together.

In regard to claim 21, Vinup et al. teach that the stimulation leads are percutaneously inserted into the desired space, col 2 lines 40-49.

In regard to claim 23, Vinup et al. teach that neurological stimulation is known to treat chronic pain, col 1 lines 13-18.

Conclusion

9. In view of the new grounds of rejection, this action is made NON-FINAL.
10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian T. Gedeon whose telephone number is (571) 272-3447. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl H. Layno can be reached on (571) 272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Carl H. Layno/
Supervisory Patent Examiner, Art Unit 3766

Carl H. Layno
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/B. T. G./
Examiner, Art Unit 3766
17 October 2008